

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: November 7, 2019

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| <p>* * * * *</p> <p>JOHN SQUADRONI,</p> <p style="padding-left: 100px;">Petitioner,</p> <p>v.</p> <p>SECRETARY OF HEALTH AND HUMAN SERVICES,</p> <p style="padding-left: 100px;">Respondent.</p> <p>* * * * *</p> | <p>*</p> <p>*</p> <p>*</p> <p>*</p> <p>*</p> <p>*</p> <p>*</p> <p>*</p> <p>*</p> <p>*</p> <p>*</p> | <p>Unpublished</p> <p>No. 16-1102V</p> <p>Special Master Gowen</p> <p>Decision on Entitlement; Ruling on the Record; Tetanus- Diphtheria-Pertussis (“Tdap”); Insufficient Proof of Causation.</p> |
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Howard S. Gold, Gold Law Firm, LLC, Wellesley Hills, MA, for petitioner.
Darryl R. Wishard, United States Department of Justice, Washington, DC, for respondent.

ENTITLEMENT DECISION¹

On September 2, 2016, John Squadroni (“petitioner”) filed a claim pursuant to the National Vaccine Injury Program.² Petitioner alleged he suffered from “back pain, lumbar pain, shoulder pain and sacral pain” as a result of receiving the Tetanus-diphtheria-pertussis (“Tdap”) vaccination on March 14, 2014. Petition at ¶1 (ECF No. 1). On August 8, 2018, petitioner filed a motion for a ruling on the record. Petitioner’s (“Pet.”) Motion (“Mot.”) (ECF No. 40). Respondent filed a response on August 21, 2018. Respondent’s (“Resp.”) Response (ECF No. 41). Petitioner filed a reply on August 27, 2018. Pet. Reply (ECF No. 42). After a full review of the entire record described below, I hereby **DENY** petitioner’s motion for a ruling resolving entitlement in his favor. I hereby find that the petitioner has not established that the Tdap

¹ Pursuant to the E-Government Act of 2002, *see* 44 U.S.C. § 3501 note (2012), because this decision contains a reasoned explanation for the action in this case, I am required to post it on the website of the United States Court of Federal Claims. The court’s website is at <http://www.uscfc.uscourts.gov/aggregator/sources/7>. **This means the Ruling will be available to anyone with access to the Internet.** Before the decision is posted on the court’s website, each party has 14 days to file a motion requesting redaction “of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b). “An objecting party must provide the court with a proposed redacted version of the decision.” *Id.* **If neither party files a motion for redaction within 14 days, the decision will be posted on the court’s website without any changes. *Id.***

² The Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-10 *et seq.* (hereinafter “Vaccine Act” or “the Act”). Hereafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

vaccination caused the onset of his back and shoulder pain. Moreover, petitioner has not submitted preponderant evidence establishing a vaccine-related injury as required by the Act. Therefore, petitioner is not entitled to compensation and his claim must be dismissed.³

I. Legal Standard

A petitioner must prove that he is entitled to compensation under the Vaccine Program. The petitioner's burden of proof is by a preponderance of the evidence. § 300aa-13(a)(1). A petitioner may demonstrate entitlement in one of two ways. The first way is to show that he suffered an injury listed on the Vaccine Injury table (a "Table" injury) with the requisite vaccination, injury, and time frame as elucidated by the Qualifications and Aids to Interpretation in which case causation is presumed. 42 U.S.C. § 100.3.

In this case, petitioner does not allege a Table injury. Therefore, petitioner has the burden of demonstrating causation-in-fact by a preponderance of the evidence. *See Cedillo v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); § 300aa-13(a)(1). To show causation-in-fact, petitioner must provide: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccination and injury." *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Petitioner must demonstrate that it was "more likely than not" that the vaccination in question caused his injury in order to meet the preponderance of the evidence standard. *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Petitioner does not need to show proof to a medical certainty. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). Petitioner must demonstrate that the vaccination in question was "not only [a] but for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006).

The Vaccine Act requires a special master to consider the record as a whole. The Vaccine Act prohibits a special master from ruling in petitioners' favor solely based on his own allegation "unsubstantiated by medical records or medical opinion." § 13(a)(1).

The process of making determinations in Vaccine Program cases for factual issues begins with consideration of the medical records which are required to be filed with the petition. § 11(c)(2). A petitioner's medical records "warrant consideration as trustworthy evidence." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2s 1525, 1528 (Fed. Cir. 1993). Medical records that are created contemporaneously with the events they describe are presumed to be accurate and complete. *Cucuras*, 993 F.2d at 1528. This presumption of accuracy and completeness is based on the linked propositions that (1) sick people visit medical professionals; (2) sick people honestly report their health problems to those professionals; and (3) medical

³ Pursuant to § 300aa-13(a)(1), in order to reach my decision, I have considered the entire record including all of the medical records, statements, expert reports, and medical literature submitted by the parties. This decision discusses the elements of the record I found most relevant to the outcome.

professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Cucuras*, 993 F.2d at 1525. If the medical records are clear, consistent, and complete, then they are afforded substantial weight. *Lowrie v. Sec’y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005).

A diagnosis and an opinion from a treating physician may be considered in the evaluation of a case. *Capizzano v. Sec’y of Health & Human Servs.*, 440 F. 3d 1317, 1326 (Fed. Cir. 2006). If contemporaneous physician’s notes are “all speculative,” a Special Master is permitted to find that such evidence is not dispositive. *See Moberly ex. rel. Moberly v. Sec’y of Health & Human Servs.*, 592 F. 3d at 1323-25 (finding that speculative notations by treating physicians were properly not dispositive on causation because “[while] several of petitioner’s treating physicians noted the temporal relationship between [petitioner’s] vaccination and petitioner’s initial brief seizures, none ever offered a solid statement...that the vaccination caused petitioner’s condition).”

Special masters should consider all of the above possibilities when evaluating the factual evidence as part of his or her responsibility to “consider all relevant and reliable evidence in the record.” *La Londe*, 110 Fed.Cl. at 204.

Petitioners often need to present a report from medical experts in support of their claim to establish a sound and reliable medical theory. *Lampe v. Sec’y of Health & Human Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). In Vaccine Act cases, expert testimony is evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993); *see also Cedillo*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec’y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). “The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.” *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

In Vaccine Program cases, the *Daubert* factors are used to weigh the proffered scientific evidence to determine their reliability. *Davis v. Sec’y of Health & Human Servs.*, 94 Fed. Cl. 53, 66-67 (2010) (“uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted”), *aff’d*, 420 F. App’x 923 (Fed. Cir. 2011). The flexible use of the *Daubert* factors to evaluate the persuasiveness and/or reliability of expert testimony in the Vaccine Program has been routinely upheld. *See, e.g., Snyder v. Sec’y of Health & Human Servs.*, 88 Fed. Cl. 706, 742-45 (2009).

A special master’s decision may be “based on the credibility of the experts and the relative persuasiveness of their competing theories” when both sides offer expert testimony. *Broekelschen v. Sec’y of Health & Human Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe v. Sec’y of Health & Human Servs.*, 219 F.3d 1357, 1362 9Fed. Cir. 2000)). However, nothing requires the acceptance of an expert’s conclusion “connected to existing data only by the *ipse dixit* of the expert,” especially if “there is simply too great an analytical gap between the data and opinion

proffered.” *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)).

II. Procedural History

Petitioner filed his claim in the Vaccine Program on September 2, 2016. Petition (ECF No. 1). Petitioner alleged that he received the Adacel Tdap vaccination on March 14, 2014 and subsequently suffered from back, lumbar, shoulder, and sacral pain as a result. Petition at ¶1. This case was assigned to my docket on September 6, 2016. (ECF No. 3). Petitioner filed his medical records on September 22, 2016. Pet. Exs. 1-6 (ECF No. 6).

On November 1, 2016, respondent filed his Rule 4(c) Report recommending against compensation. Resp. Report at 1 (ECF No. 7). Respondent objected to compensation for two reasons. First, respondent argued petitioner has a bilateral subdeltoid bursitis of unknown cause which does not meet the requirements of a Shoulder Injury Related to Vaccine Administration (“SIRVA”). Resp. Report at 7. Second, respondent argued the Tdap vaccine did not cause or significantly aggravate petitioner’s pre-vaccination conditions of low back pain, joint arthropathy, and lumbar stenosis. *Id.*

On November 9, 2016, I ordered both parties to file expert reports addressing the issue of vaccine causation. *See* Scheduling Order (ECF No. 8). Petitioner filed an expert report from Dr. M. Eric Gershwin on April 25, 2017. Pet. Ex. 7 (ECF No. 15). Respondent filed a responsive report from Dr. Chester Oddis on July 10, 2017. Resp. Ex. A (ECF No. 23).

I held a Rule 5 status conference on September 20, 2017. During the status conference, I noted that petitioner is proposing a vaccine causation theory whereby his “complicated emotional state predisposed him to have a more extreme reaction to the vaccine.” Scheduling Order at 1 (ECF No. 24). I stated that there is a lack of a clear connection between the vaccine and petitioner’s alleged injury. *Id.* As a result, I ordered petitioner to file psychiatric records, an evaluation explaining his severe somatic response to the vaccination, and a supplemental expert report addressing petitioner’s psychiatric reaction to vaccination and the physiological process of pain moving from petitioner’s arms to other regions of his body. *Id.* at 2.

Petitioner requested four extensions of time to secure an additional expert report. (ECF Nos. 25, 27, 29, 31). Following the fourth motion for an extension of time on April 21, 2018, respondent filed a motion objecting to an additional extension of time and moved for summary judgment. (ECF No. 32). On April 23, 2018, I granted petitioner’s motion for an extension of time and deferred ruling on respondent’s motion for summary judgment. *See* Order (ECF No. 33).

Petitioner filed a self-reported pain calendar documenting his alleged condition on May 11, 2018. Pet. Ex. 8 (ECF No. 34). On the same day, petitioner filed an expert report from Dr. Raymond Singer, PhD, a neuropsychologist, addressing causation. Pet. Ex. 9 (ECF No. 35). He opined that the petitioner was in good health prior to the vaccine, not acknowledging any of his prior musculoskeletal complaints, that there was a temporal relationship between the vaccine and onset of symptoms and diagnosed a psychosomatic disorder for which a full neuropsychological evaluation should be done. Pet. Ex. 9 at 9. This examination was never completed.

I held a status conference on May 31, 2018. During the status conference, I noted Dr. Singer appeared to make his diagnosis based on petitioner's medical records rather than a direct evaluation even though he was rendering a psychological diagnosis. Scheduling Order at 1 (ECF No. 37). Second, I noted the petitioner's pain diary did not indicate if it was created at the time petitioner was experiencing the pain. *Id.* Third, I stated that there may not be a sufficiently strong logical nexus between vaccination and petitioner's alleged injury such that a psychological symptom amplification syndrome can be considered a vaccine injury. *Id.* at 2. Petitioner contended his injury was back and shoulder pain that he experienced after the vaccination and not that the vaccine caused his psychological condition. I ordered petitioner to file an affidavit detailing how and when the filed pain calendar was created. *Id.* During the status conference, the parties agreed to a ruling on the record and I ordered petitioner to file the appropriate motion. *Id.* I also denied respondent's earlier motion for summary judgment as moot. *Id.*

On June 14, 2018, petitioner filed an affidavit stating he created the pain diary contemporaneously. (ECF No. 38). On July 16, 2018, petitioner filed a motion to amend the schedule for filing a motion for a ruling on the record. (ECF No. 39). Petitioner requested to have until August 9, 2018 to file the motion. (ECF No. 39). Petitioner's motion was granted on July 17, 2018. Order Non-PDF, Granting Motion to Amend Schedule.

On August 8, 2018, petitioner filed a motion for a ruling on the record. Pet. Mot. Respondent filed a response to the motion on August 21, 2018. Resp. Response. Petitioner filed a reply on August 27, 2018. Pet. Reply (ECF No. 42).

This motion is now ripe for adjudication.

III. Relevant Medical Facts

A. Petitioner's Medical Records Prior to Vaccination

Petitioner has a significant medical history of multiple chronic conditions including hyperlipidemia, hypertension, osteoarthritis, diabetes, and ulnar nerve neuropathy. Pet. Ex. 4 at 5-6. Petitioner had previously undergone neck surgery. *Id.*

The earliest medical record filed is petitioner's visit with Dr. Anatoliy Fortenko for low back pain on March 1, 2011. *Id.* The visit note stated petitioner had an episode of pain in the low back and buttocks approximately three weeks prior that had since resolved. *Id.* Dr. Fortenko diagnosed petitioner's complaint as lumbosacral radiculopathy⁴ and facet arthropathy⁵ and

⁴ Lumbosacral radiculopathy is disease of the nerve roots in the lower back as a result of inflammation or impingement by a tumor or bony spur. *Dorland's Illustrated Medical Dictionary* 32nd ed. (2012) (hereinafter "*Dorland's*") at 1571.

⁵ Facet arthropathy is also known as osteoarthritis that is centered within the facet joints with disk degeneration and pain that is most common in the lumbar region. *Dorland's* at 1344.

prescribed meloxicam.⁶ *Id.* at 7.

On a March 28, 2011 telephone encounter with Dr. Sherilynn Cooke, petitioner complained of feeling ill after taking Amlodipine.⁷ *Id.* at 24-25. Petitioner stated during the phone call that the prescribed meloxicam helped with his back and ankle pain. *Id.* During a subsequent telephone encounter with Dr. Cooke on June 6, 2011, petitioner complained of continued back pain with difficulty with urination and tingling/numbness around the cervical area. *Id.* at 31-32. Dr. Cooke recommended a follow-up visit with Dr. Fortenko and continuing the meloxicam medication. Petitioner spoke with Dr. Fortenko by telephone on June 9, 2011. *Id.* at 38. Petitioner reported the severe back pain resolved with Aleve but there was still numbness in the left arm which petitioner attributed to his previous neck surgery. *Id.*

During an October 18, 2011 telephone encounter with Dr. Cooke, petitioner complained of occasional hip pain without pain radiating down the leg. *Id.* at 50-51. Dr. Cooke diagnosed petitioner's complaint as low back pain. *Id.*

Petitioner next saw a physician in-person on November 15, 2011. On November 15, 2011, petitioner saw Dr. Ekaterina Malinovsky for left buttock and posterior thigh pain that had persisted intermittently for a year. An MRI of petitioner's lumbar spine showed "[m]ultilevel spondylotic disc disease⁸ and facet joint arthropathy of the lumbar spine." Pet. Ex. 4 at 61. Dr. Malinovsky assessed petitioner with sciatica and stated the pain in petitioner's buttock and leg could be due to a muscle spasm rather than osteoarthritis. *Id.*

On January 29, 2013, petitioner called the Kaiser Permanente call center with a complaint of severe pain in the right foot. *Id.* at 130-32. Petitioner stated that the pain was a flare-up of gout which he attributed to eating crab salad. *Id.* Petitioner requested a cortisone shot for the pain. *Id.* Petitioner saw Dr. Frank Shic on January 30, 2013. Dr. Shic noted great toe pain, assessed gout, and administered a shot of lidocaine and depomedrol. *Id.* at 138. Petitioner's active medical history at this point matched that from March 1, 2011. *Id.* at 137.

Petitioner's next substantive interaction with medical professionals was approximately nine months later, on September 25, 2013, when he presented to Dr. Shic with lower back pain. *Id.* at 190. Petitioner complained of lower back pain and Dr. Shic noted that petitioner endorsed numbness and tingling after waking up one morning. *Id.* Dr. Shic noted that petitioner had an MRI in 2011 that showed spondylotic changes and moderate to severe central stenosis at L4-L5 and L5-S1. *Id.* Dr. Shic's physical examination found "exquisite right sided lumbar tenderness", assessed him with lower back pain and prescribed meloxicam. *Id.* at 191. In a telephone encounter with Dr. Shic, on October 3, 2013 petitioner reported that his lower back pain was better. *Id.* at 200. Dr. Shic opined that petitioner's lower back pain was likely due to osteoarthritis rather than

⁶ Meloxicam is a nonsteroidal anti-inflammatory drug ("NSAID") that is commonly used to relieve the symptoms of arthritis. Mayo Clinic, *Meloxicam (Oral Route)*, <https://www.mayoclinic.org/drugs-supplements/meloxicam-oral-route/description/drg-20066928>, (last accessed July 19, 2019).

⁷ Amlodipine is a prescription drug used to treat high blood pressure.

⁸ Degenerative joint disease in the lumbar vertebrae and the vertebral disks that causes pain and stiffness. *Dorland's* at 1754.

a strain. *Id.* at 201.

Petitioner presented to Dr. Shic on March 14, 2014 with complaints of increased right jaw, shoulder, and arm stiffness following a deer tick bite approximately two weeks prior and bilateral hand pain. *Id.* at 262. Petitioner also reported “increased interpersonal stress with neighbor and female crew team he was coaching.” *Id.* Dr. Shic’s physical exam showed “exquisite wrist tenderness.” *Id.* at 263-64. Dr. Shic assessed petitioner with osteoarthritis of bilateral hands and injected lidocaine and depomedrol into petitioner’s first MCP⁹ joints as treatment. *Id.* During the visit, petitioner received the Pneumococcal Polysaccharide, 23 Valent (“PPV/23”) and Tdap vaccinations in question. *Id.* at 265. The medical assistant’s note stated that petitioner had no contraindications for the vaccinations. *Id.* Dr. Shic also assessed petitioner with “stress,” and referred him to a Behavioral Medicine Specialist (“BMS”). *Id.* at 265.

B. Petitioner’s Medical Record Post-Vaccination

On March 26, 2014, petitioner called his primary care provider, complaining about “diffuse muscle cramping after [T]dap shot and remembers having a similar reaction in college that lasted three weeks.” Pet. Ex. 4 at 270. Dr. Shic noted that this was likely a side effect of the vaccine. *Id.*

Petitioner saw Dr. April Young, a psychologist, on March 28, 2014. *Id.* at 277-78. She noted that petitioner was referred by Dr. Shic for depression and stress. *Id.* at 277. Petitioner reported depression with an onset of 30 years prior. Dr. Young recommended a functional assessment and further supportive consultation. *Id.* A second appointment was scheduled for April 11, 2014. *Id.*

In an April 9, 2014 telephone encounter with Dr. Shic, petitioner complained of ongoing muscle aches after Tdap shot. *Id.* at 286-87. Dr. Shic diagnosed petitioner with myalgia and ordered a creatine kinase test and complete blood count with differential for petitioner. *Id.* Petitioner’s lab results from April 11, 2014 showed high LDLs, high cholesterol, high hemoglobin A1c, and high blood glucose. *Id.* at 290-94. Petitioner had a normal creatine kinase and normal white blood cell differential.¹⁰ *Id.*

Petitioner saw Dr. Young again on April 11, 2014 where he reported pain for “the past month after receiving his tetanus shot.” *Id.* at 297. He stated that he is “nearly paralyzed” and unable to raise his arms, and had difficulty walking. *Id.* Dr. Young diagnosed petitioner with depression. *Id.*

The same day, April 11, 2014, petitioner saw Dr. Shic for muscle cramps and ongoing “diffuse shoulder and thigh myalgias.” *Id.* at 301. Petitioner also reported trouble sleeping. *Id.* A physical exam revealed deltoid and quadriceps tenderness. *Id.* Dr. Shic assessed petitioner with adverse drug reaction, “likely slowly resolving tdap reaction.” *Id.* at 302. Dr. Shic prescribed

⁹ The metacarpophalangeal joints (“MCP”) are located between the metacarpal bones and phalanges of the fingers.

¹⁰ Petitioner’s creatine kinase value was 28 U/L with a reference range of ≤ 200 U/L, petitioner’s white blood cell count and count of white blood cell components were all within normal ranges. Pet. Ex. 4 at 293-94.

hydrocodone-acetaminophen. *Id.* Labs were pending to check for rhabdomyolysis [sic].¹¹ *Id.*

Petitioner contacted the Kaiser Permanente call center on April 14, 2014 complaining of severe pain and pain on his scapula. *Id.* at 316. Petitioner stated he had stopped taking Vicodin, but had taken “4 asa”¹² which made him feel better four hours later. *Id.*

Dr. Shic returned petitioner’s call that same day to report the test results. *Id.* at 306. The primary diagnosis was diabetes mellitus, type 2. *Id.* at 306. Petitioner was prescribed an oral tablet of Metformin¹³ 500 mg and a diabetes monitoring kit. *Id.* at 307. In a letter to petitioner dated April 14, 2014, Dr. Shic wrote, “...you have diabetes which could explain some of your recent symptoms.” *Id.* at 309.

In a telephone encounter on April 19, 2014 at 8:38 AM, with Dr. Eric Crisostomo, petitioner reported moderate to severe right arm pain since Tdap vaccination. *Id.* at 322. Petitioner stated that the pain may have extended to his other arm and legs. *Id.* at 322-23. Petitioner reported pain with overhead arm movements but denied skin redness or swelling. *Id.* Dr. Crisostomo commented that petitioner’s symptoms did not sound like an infection due to the lack of inflammation but questioned if petitioner’s reaction was idiosyncratic. *Id.*

Later that day, petitioner saw Dr. Prathima Jayaram. *Id.* at 325-357. Petitioner reported pain all over his body, especially in his upper body and indicated the pain has continued for one month. *Id.* at 326-27. Petitioner reported the pain as 15 out of 10 and described his pain as “stabbing.” *Id.* at 326. His range of motion in his bilateral shoulder was “significantly decreased.” *Id.* Dr. Jayaram described the physical exam of petitioner’s upper extremities as “abnormal,” and noted muscle tenderness and restricted range of active motion. *Id.* at 327. Dr. Jayaram assessed petitioner with bilateral shoulder joint pain and hip pain with a differential diagnosis of polymyalgia rheumatica (“PMR”).¹⁴ *Id.* Dr. Jayaram prescribed petitioner 15 mg/per day of prednisone and referred petitioner to Dr. Sarah Beckman Gratton, a rheumatologist for further evaluation. Dr. Jayaram ordered tests for a PMR diagnosis which came back negative except for high ESR and CRP levels.¹⁵ *Id.* at 334-45. Petitioner had normal IgG and IgE levels and a negative ANA. *Id.*

On April 21, 2014, petitioner met with Dr. Gratton. *Id.* at 352. Dr. Gratton noted that

¹¹ Rhabdomyolysis is a disease involving the disintegration or dissolution of muscle and is associated with the excretion of myoglobin in the urine. *Dorland’s* at 1637. Petitioner’s medical records do not indicate if these lab results were reported and do not indicate if petitioner was ever diagnosed with rhabdomyolysis.

¹² “ASA” refers to acetylsalicylic acid, the active ingredient of aspirin.

¹³ Metformin is a drug used to treat high blood sugar levels that are caused by a diabetes mellitus or sugar diabetes called type 2 diabetes. <https://www.mayoclinic.org/drugs-supplements/metformin-oral-route/description/drg-20067074>

¹⁴ Polymyalgia rheumatica is a syndrome characterized by joint and muscle pain and a high erythrocyte sedimentation rate (“ESR”). *Dorland’s* at 1490.

¹⁵ Petitioner’s ESR level was 26 mm/hr with a reference range of 0-20 mm/hr. Petitioner’s CRP level was 4.4 mg/dL with a reference range of ≤ 0.5 mg/dL.

petitioner was referred to rheumatology because of bilateral shoulder pain and upper arms, along with corresponding bilateral hip and thigh pain,” and the symptoms got worse after receiving the Tdap vaccination. *Id.* Petitioner reported pain in his right shoulder after the Tdap vaccination and experienced subsequent stiffness in the right shoulder that progressed to the left shoulder. *Id.* He stated the pain, “‘feels like a skewer’” from the right to the left arm. *Id.* at 353. In the musculoskeletal examination of petitioner, Dr. Gratton found that he had a normal gait, tender bilateral deltoid, and pain at the anterior hip against resistance. *Id.* at 356. In an exam of petitioner’s joints, she found that petitioner had full nontender range of motion, no pain over elbows, wrists, knees, ankles, mid-feet, or hips (with limited bilateral inner rotation). *Id.* Dr. Gratton diagnosed petitioner’s symptoms as being consistent with bilateral deltoid bursitis. *Id.* at 358-59. Dr. Gratton stated that petitioner has “acute onset of soft tissue pain following vaccination of the upper extremities and the proximal lower extremities with gradual improvement that he has associated with Alka-Seltzer (with antihistamine component), raising question of immune system activation.” *Id.* at 358. She stated, “Currently the symptoms and exam are consistent with bilateral deltoid bursitis.” *Id.* She noted that “this is atypical for PMR in the process (the tenderness diffuse UE at the start), he is young for this diagnosis and the ESR is very minimally elevated (normal for age).” *Id.* In her note, Dr. Gratton included an abstract for an article by Soriano, et al.¹⁶ which connects giant cell arteritis and PMR to the influenza (“flu”) vaccine. *Id.* at 359-61. She prescribed him 10 mg/per day of prednisone and recommended he follow his blood-glucose level closely. *Id.* at 359. Additionally, Dr. Gratton advised against shoulder injections, but petitioner also deferred a referral to physical therapy. *Id.*

On April 23, 2014, petitioner saw his psychiatrist, Dr. Young for a follow-up visit. Dr. Young documented that petitioner stated he had an “autoimmune reaction to the tetanus shot” and was able to relate some of his physical pain to his “unresolved/unaddressed emotional issues.” Pet. Ex. 4 at 371. Petitioner returned to Dr. Young on May 2, 2014 and reported that he stopped taking medication to determine his pain level. *Id.* at 375. She noted that petitioner related his physical difficulties to not being able to participate in the level of elite training he had been previously engaging in and he described a “clear delineation [in] his well-being prior to and following neck surgery.” *Id.* at 375.

On May 11, 2014, Dr. Gratton followed-up with petitioner. Pet. Ex. 4 at 379. She noted that petitioner began the prednisone, in addition to Alka Seltzer and had improvement. *Id.* Petitioner also took his Metformin. *Id.* He reported that he stopped taking the prednisone, but pain on his left side returned, although not as severe. *Id.* He restarted taking prednisone and reported feeling 80% better. *Id.* Petitioner also reported that he was able to sleep normally and his symptoms in his hips resolved. *Id.* The note from the telephone encounter states that petitioner was “treated for bursitis (vs. atypical PMR) possibly related to vaccination. If symptoms return with slow taper of prednisone, will consider more typical treatment of PMR.” *Id.* Dr. Gratton prescribed a prednisone taper over a four-week period. *Id.* at 381.

On May 27, 2014, petitioner called Dr. Gratton and reported issues relating to his medication. *Id.* at 387. Petitioner reported that severe pain returned, mostly in his shoulders down to his arms, when he stopped prednisone completely. *Id.* Dr. Gratton discussed a shoulder

¹⁶ Alex Soriano, et al., *Giant Cell Arteritis and Polymyalgia Rheumatica After Influenza Vaccination: Report of 10 Cases and Review of the Literature*, 21 *Lupus* 153 (2012).

injection and a faster prednisone taper. *Id.* Petitioner was referred to radiology for an x-ray of his shoulders. *Id.*

On May 29, 2014, petitioner spoke to his primary care physician, Dr. Shic. *Id.* at 396. Dr. Shic's noted that petitioner was being seen by rheumatology and "started on prednisone for idiosyncratic reaction to tetanus [vaccine]." *Id.* Dr. Shic diagnosed petitioner with adverse drug reaction and noted that petitioner was not checking his blood sugars. *Id.* Dr. Shic ordered a repeat HGA1c. *Id.*

On May 30, 2014, petitioner returned to psychologist, Dr. Young. *Id.* at 400. Petitioner reported that if it was not for an ankle injury, broken neck (from a pickup basketball game) and "the injection," he would be an elite athlete. *Id.* He informed Dr. Young that he was planning on going to the northwest to train over the summer to rebuild his muscles that "the injection" caused to deteriorate. *Id.* Dr. Young diagnosed petitioner with an "adjustment disorder." *Id.* at 399.

Petitioner had x-rays of his shoulders on June 16, 2014. Pet. Ex. at 407. The x-ray impression was degenerative changes of bilateral acromioclavicular ("AC") joints with no evidence of calcific tendinopathy. *Id.* at 408. However, Dr. Gratton noted that the degenerative changes in the AC joint are common "wear and tear" changes which do not explain petitioner's shoulder pain complaints. *Id.* at 415. Petitioner had additional labs completed on July 9, 2014 where his ESR and serum CRP were normal.¹⁷ *Id.* at 421.

On July 11, 2014, petitioner had a follow-up exam with Dr. Gratton. *Id.* at 422. Dr. Gratton reviewed petitioner's medical history, where she noted petitioner reported that he "has been in pain for forty years. He was hit by cars when cycling on seven occasions, had numerous injuries...broke his neck and ankle." *Id.* The reported history again stated that following the Tdap vaccination in the right shoulder, he experienced stiffness and pain that progressed to his left shoulder. *Id.* Petitioner also reported that he had a similar vaccination following Tdap vaccination in college that lasted for three weeks. *Id.* Petitioner had mild impingement on resisted shoulder extension but did not have any pain to palpation or synovitis over elbows or wrists. *Id.* at 426.

On an August 15, 2014 telephone encounter with Dr. Shic, petitioner reported pain in the lower sacrum area. Dr. Shic ordered an x-ray which was completed on August 29, 2014. The sacrum/coccyx x-ray found minimal degenerative spurring of the sacroiliac joints without erosive change, minimal degenerative endplate changes at the lower lumbar spine, and no definite fracture or malalignment. *Id.* at 452. Dr. Shic conducted a physical exam of petitioner on the same day and in the musculoskeletal exam, Dr. Shic found no lumbosacral tenderness. *Id.* at 457.

In a September 4, 2014 telephone encounter with Dr. Joseph Reena, petitioner reported prednisone helped with his aches except for his sacrum pain. *Id.* at 470. Petitioner reported to Dr. Gratton in a telephone encounter on September 5, 2014 that Aleve was helpful for his lower back. *Id.* at 477. By September 16, 2014, petitioner had stopped taking Aleve and was taking aspirin for the pain. *Id.* at 481.

An additional lab test on September 16, 2014 found normal CRP levels, normal ESR levels,

¹⁷ Petitioner's ESR level was 10 mm/hr with a reference range of 0-20 mm/hr. Petitioner's CRP level was 0.5 mg/dL with a reference range of ≤ 0.5 mg/dL. Pet. Ex. 4 at 421.

normal white blood cell levels (including neutrophils, lymphocytes, eosinophils, and basophils). *Id.* at 492-94. A September 16, 2014 MRI of the lumbar spine without contrast showed spondyloarthropathy in the lumbar spine which was most pronounced at the L4-L5 and L5-S1 levels. *Id.* at 499. The MRI impression stated there was mild interval progression since petitioner's previous MRI on February 13, 2011. *Id.* at 500. The differential diagnosis from the MRI included post-inflammatory or traumatic changes due to a "subtle area of increased signal on the T2 fat sat sequence in the right posterior paraspinal musculature." *Id.* at 503.

In a September 24, 2014 visit with Dr. Linda Choe, a physiatrist, petitioner reported his pain was not isolated within the sacral region. *Id.* at 506. Dr. Choe noted a normal heel and toe gait with a slight shift to the left in petitioner's spinal ribs and pelvis. *Id.* Dr. Choe also noted a crease in the right lateral rib case and TTP right sacral region. *Id.* Dr. Choe assessed petitioner with lumbar spondylosis. *Id.* at 507.

On October 5, 2014, petitioner saw David Morris, D.C., a chiropractor. Pet. Ex. 5. Petitioner reported lower back pain, bilateral shoulder pain, buttock and tailbone pain and legs numbing and tingling. *Id.* at 1. Dr. Morris found petitioner to have a severe antalgic lean to the left from his lower back or pelvis as a result of muscle spasms that may have been due to vaccinations. Pet. Ex. 5 at 4. Petitioner returned to Dr. Morris for six appointments. *Id.* at 5. A note from October 22, 2014, states petitioner is "walking more without aggravation-less spasms." *Id.* On October 26, 2014, Dr. Morris noted, "severe deep aching in mid back." *Id.* at 5.

On October 14, 2014, petitioner saw Dr. Philip Ranheim. Pet. Ex. 6. Petitioner reported shoulder and sacrum pain after receiving the Tdap vaccination. *Id.* at 7. Dr. Ranheim documented a normal physical exam. *Id.* at 6. Dr. Ranheim also reviewed petitioner's medical records and noted petitioner's high blood sugars, stating, "Interestingly with the pain his blood sugars went as high as 280-perhaps this was in conjunction with the prednisone but I'm not sure." *Id.* at 5. Dr. Ranheim assessed petitioner with an "abnormal pain and muscle spasm after vaccine reportedly" but stated petitioner was doing better after seeing Dr. Morris. Pet. Ex 6 at 4.

Petitioner's last filed medical record is a February 5, 2016 visit with Dr. Gratton. *Id.* at 558-59. Petitioner's symptoms and medical history from the visit are not substantively different from previous records. *Id.* at 558-59. The petitioner addresses the intervening interval of time through his pain diary discussed below.

C. Petition

On September 2, 2016, petitioner filed his petition claiming a March 14, 2014 Tdap vaccination caused his back pain, lumbar pain, shoulder pain, and sacral pain. Petition at 1. Petitioner asserts that following the Tdap vaccination, he began to "feel unwell to the point of unconsciousness." Petition at ¶ 4. Petitioner asserts he had upper back spasms on the night of March 16, 2014 which was assessed as a "likely [T]dap side effect" by Dr. Frank Shic on March 26, 2014. *Id.* at ¶¶ 6-7.

Petitioner asserts complaints of diffuse shoulder and thigh myalgias on April 11, 2014 for which he was seen on April 21, 2014 by Dr. Sarah Gratton, a rheumatologist. *Id.* at ¶ 11. Petitioner underwent prednisone therapy which led to some improvement in petitioner's condition. *Id.*

Petitioner started to have pain in the sacrum¹⁸ area in October 2014. *Id.* at ¶ 13. Petitioner asserts that he continues to experience “pain along the right side of the sacrum and the entire right leg.” *Id.* at ¶ 14. As a result, petitioner asserts that he has been “unable to work or unable to participate in his physical activities.” *Id.* at ¶ 15.

D. Dr. Gershwin’s Expert Report

On April 25, 2017, petitioner filed an expert report from Dr. M. Eric Gershwin.¹⁹ Pet. Ex. 7. Dr. Gershwin disagreed with the diagnoses provided by petitioner’s treating physicians. *Id.* at 2. Dr. Gershwin contended that petitioner’s myalgias that followed the Tdap vaccination was misdiagnosed by petitioner’s rheumatologist, Dr. Gratton. *Id.* at 1-2. Dr. Gershwin opined that the elevated levels of petitioner’s ESR and CRP were consistent with his poorly controlled diabetes rather than indicative of atypical PMR. *Id.* Dr. Gershwin asserted that as a result of the PMR misdiagnosis and incorrect subsequent treatment, petitioner’s problems “became persistent” instead of resolving. *Id.*

Dr. Gershwin stated that petitioner had a history of “significant musculoskeletal problems prior to the vaccine” but that it was “more likely than not that he did develop some myalgias following [vaccination].” *Id.* Dr. Gershwin contended, however, that petitioner was presumptively misdiagnosed with polymyalgia rheumatica when there was no significant evidence to support that diagnosis. *Id.* at 2. He stated that petitioner’s elevated inflammatory makers of ESR and CRP were more consistent with petitioner’s poorly controlled diabetes, but instead he was misdiagnosed with PMR and treated with steroids. *Id.* at 2. The waxing and waning dosages of steroids only made petitioner’s myalgias worse and the suggestion that his myalgias could be autoimmune made the petitioner’s response “emotional,” and his problems became chronic. *Id.* at 2. Dr. Gershwin concluded that petitioner was instead suffering from fibromyalgia. *Id.* at 2. He stated, “I should note that vaccination does not produce fibromyalgia.” *Id.* Dr. Gershwin continued, stating, “It is [petitioner’s] somatic reaction to the events that occurred following the vaccine that led to his diffuse pain syndrome.” *Id.* In his review of petitioner’s medical records,

¹⁸ The sacrum is the triangular bone below the lumbar vertebrae. The sacrum is directly above the coccyx (tailbone). *Dorland’s Illustrated Medical Dictionary* 32nd ed, (2012) (hereinafter “*Dorland’s*”) at 1662.

¹⁹ Dr. Gershwin received his bachelor’s degree *summa cum laude* from Syracuse University in 1966 and his M.D. from Stanford University in 1971. Pet. Ex. 7a at 1. Dr. Gershwin received a Master’s Degree in Astronomy and Astrophysics from the Centre for Astrophysics and Supercomputing in Melbourne, Australia in 2002. *Id.* Dr. Gershwin completed his internship and residency at the Tufts-New England Medical Center in Boston, MA in 1973. *Id.* at 2. Dr. Gershwin was a Clinical Associate in Immunology and the National Institutes of Health from 1973 to 1975. *Id.* Since 1975, Dr. Gershwin held academic appointments as Assistant Professor of Medicine in Rheumatology and Allergy, Professor of Medicine in Rheumatology and Allergy, The Jack and Donald Chia Professor of Medicine in the Division of Rheumatology/Allergy and Clinical Immunology, and Distinguished Professor of Medicine in the Division of Rheumatology/Allergy and Clinical Immunology at the University of California, Davis. *Id.* at 1-2. Dr. Gershwin is board certified in internal medicine with a subspecialty of rheumatology and board certified in allergy and clinical immunology. *Id.* Dr. Gershwin is the Director of the Allergy-Clinical Immunology Program and Chief of the Division of Rheumatology/Allergy and Clinical Immunology at the University of California School of Medicine, Davis. *Id.* Dr. Gershwin is the holder of multiple patents related to rheumatology and immunology, is an editor on multiple immunology journals, and has extensively published original research articles and books related to immunology. *Id.* at 2, 6, 9-123. Dr. Gershwin has served as an expert witness in multiple Vaccine Program cases.

Dr. Gershwin noted that petitioner complained of muscle cramps and diffuse myalgias starting approximately two weeks after petitioner's Tdap vaccination on March 14, 2014. *Id.* at 1. Dr. Gershwin cited literature concerning fibromyalgia's relationship with a patient's stress response system²⁰ as well as how fibromyalgia's heightened pain sensitivity can foreshadow chronic pain.²¹ Although Dr. Gershwin put the label of fibromyalgia on the petitioner's condition, the focus of his analysis was on the contribution of psychological stress, victimization and the modulation of pain information in the development of his pain syndrome.

Dr. Gershwin posits that petitioner became "fixated over a common reaction" following the Tdap vaccination that was amplified by his treating physicians' suggestion that his condition could be PMR, an autoimmune condition. *Id.* at 2. This fixation then precipitated further somatic issues. *Id.* Dr. Gershwin concluded that without the Tdap vaccination, in tandem with the incorrect treatment of petitioner as a result of a misdiagnosis, petitioner suffered his long-term pain injuries. *Id.* Dr. Gershwin stated the "timing of the 'aches' following the vaccination was appropriate" without reference to the medical record or analysis. *Id.* at 3.

E. Dr. Oddis' Expert Report

On July 10, 2017, respondent filed a responsive expert report from Dr. Chester Oddis.²² Resp. Ex. A. Dr. Oddis opined that petitioner's pain pre-dated the Tdap vaccination, stating that, "[petitioner's] symptoms are really on a continuum and that they essentially don't vary significantly from the first time that he presented to his family doctor in 2011." Resp. Ex. A at 3. Dr. Oddis noted that petitioner complained of diffuse musculoskeletal symptoms that included, back, shoulder, hip and neck pain on several occasions prior to the vaccination. *Id.* He observed that the day the petitioner received the vaccination, petitioner was complaining of increased jaw, shoulder, arm and bilateral hand pain. *Id.*; *see also* Pet. Ex. 4 at 263.

Dr. Oddis disagreed with petitioner's treating rheumatologist on the diagnosis of PMR and agreed with Dr. Gershwin that petitioner's symptoms were inconsistent with PMR. *Id.* at 3. Dr. Oddis explained that PMR is characterized by significant morning stiffness of the proximal upper and lower extremity musculature that often lasts several hours and the inflammatory markers are

²⁰ Lesley M. Arnold, *The Pathophysiology, Diagnosis and Treatment of Fibromyalgia*, 33 *Psychiatric Clinics of North America* 375 (June 2010). [Pet. Ex. 7D].

²¹ Roland Staud, *Abnormal Pain Modulation in Patients with Spatially Distributed Chronic Pain: Fibromyalgia*, 35 *Rheumatic Disease Clinics of North America* 263 (May 2009). [Pet. Ex. 7S].

²² Dr. Oddis received his bachelor's degree in biochemistry from the University of Pittsburgh in 1976 followed by his M.D. from the Pennsylvania State University College of Medicine in 1980. Resp. Ex. B at 1. Dr. Oddis completed his internship and residency in internal medicine at the Pennsylvania State University College of Medicine in 1984 and a fellowship in rheumatology at the University of Pittsburgh School of Medicine in 1987. *Id.* Dr. Oddis has held academic positions at the University of Pittsburgh School of Medicine, Division of Rheumatology and Clinical Immunology since 1987. *Id.* at 2. Dr. Oddis currently is a Professor of Medicine in the Division of Rheumatology and Clinical Immunology, the Associate Director of the Rheumatology Fellowship Training Program, and Director of the Myositis Center at the University of Pittsburgh. *Id.* Dr. Oddis is board certified in internal medicine and rheumatology. Dr. Oddis is an active medical researcher and has published extensively in the field of rheumatology and myositis. *Id.* at 4-24. Dr. Oddis is an active clinical practitioner at the University of Pittsburgh. *Id.* at 25. Dr. Oddis has served as an expert witness in multiple Vaccine Program cases.

invariably elevated. *Id.* Further, the peak age group for PMR are those in their seventies and eighties. *Id.* Dr. Oddis stated that petitioner is quite young for the PMR diagnosis; had only a *slightly elevated ESR*-and the degree of elevation was not within the range associated with PMR. *Id.*

Dr. Oddis disagreed with Dr. Gershwin's diagnosis of fibromyalgia. Resp. Ex. at 3. Dr. Oddis observed that petitioner was never diagnosed with fibromyalgia and stated that whether petitioner actually has fibromyalgia is a moot point. *Id.* at 4. Dr. Oddis, once again, emphasized that petitioner's pain syndrome predated the administration of the Tdap vaccination. *Id.* He argued that Dr. Gershwin's recommendation of counseling ignored the fact that petitioner received psychological counseling within days of receiving the vaccination and that counseling continued simultaneously with petitioner's treatment for pain. *Id.*; *see also* Pet. Ex. 4 at 262, 296, 370. Dr. Oddis stated that petitioner's treating psychiatrist did not attribute petitioner's chronic pain or any exacerbation of pain related to the Tdap vaccination as the cause of petitioner's depression or anxiety. *Id.* at 4.

Dr. Oddis attributed the amplification of petitioner's pain syndrome to his longstanding depression, anxiety and significant interpersonal problems. *Id.* As a result, he argued, the Tdap vaccine "gave the petitioner another presumptive cause for his chronic pain." *Id.* Dr. Oddis concluded that petitioner's chronic musculoskeletal complaints and pain syndrome "clearly predated" the Tdap vaccination. *Id.*

F. Dr. Singer's Expert Report

On May 14, 2018, petitioner filed a supplemental expert report from Dr. Raymond Singer, PhD.²³ Pet. Ex. 9. Dr. Singer is a neuropsychologist with experience in forensic matters involving toxic insult. In this case, Dr. Singer was asked to address two questions I posed in the Rule 5 Order: 1) Why did petitioner experience such an intense psychiatric reaction to the vaccination? 2) How do you explain the physiological process of the pain moving from the arm/shoulder to the lower body and then on to multiple places on the upper and lower body? *See* Rule 5 Order at 2. Dr. Singer prefaced his report with various references to the Tdap package insert and to the presence of aluminum and formaldehyde in the formula without addressing their role in petitioner's condition. Pet. Ex. 9 at 2-5. He then focused his report on

²³ Dr. Singer is a forensic and clinical neuropsychologist. Pet. Ex. 10 at 2. He received his bachelor's degree in psychology in 1972 from the University of Rochester. *Id.* Dr. Singer then received a master's degree and a PhD in psychology from Washington State University in 1975 and 1978, respectively. *Id.* Dr. Singer received training as a post-doctoral fellow in environmental epidemiology through the National Institutes of Health, Environmental Health Sciences from 1979 to 1981 and as a fellow at the Mount Sinai School of Medicine Department of Community Medicine, Environmental Sciences Laboratory from 1981 to 1982. *Id.* at 2-3. Dr. Singer was a post-doctoral fellow in biological psychiatry through the National Institutes of Health at New York University Medical center in 1978. *Id.* at 3. Dr. Singer is a fellow in the National Academy of Neuropsychology, American College of Professional Neuropsychology, American Psychological Association, and Association for Psychological Science. *Id.* Dr. Singer has served as a consultant for neuropsychological, neurobehavioral, and neurotoxicological diagnostics and as an expert witness in toxic chemical litigation since 1983. *Id.* at 4. Dr. Singer has conducted research and published extensively in the area of neuropsychology and neurotoxicology. *Id.* at 7-19.

the questions raised in the Rule 5 Order. *Id.* Dr. Singer provided a summary of psychosomatic symptoms:

Psychosomatic symptoms [are] a way to describe medically unexplained symptoms, symptoms of unknown origin, hypochondria and somatoform disorders. Other terms include somatic symptoms, functional somatic syndromes and deception syndromes. A simplified view of the condition uses the term “symptom amplification.”

Id. at 5.

Dr. Singer explained that when petitioner first presented to his rheumatologist, Dr. Gratton, petitioner explained that the pain progressed from his right to his left arm and that “this type of progression of pain is not typical.” *Id.* Dr. Singer also observed that the petitioner’s description of the pain traveling from the shoulder to the buttocks/groin area is “not entirely consistent with an infectious process which would spread more locally or along nerve patterns.” *Id.* at 6. Dr. Singer opined that the petitioner’s local reaction to the Tdap vaccination created a “cascading series of events, both physical and mental, made worse by petitioner’s psychological vulnerabilities.” *Id.* at 8.

Dr. Singer referenced the petitioner’s psychological history from Dr. Young’s progress note from April 23, 2014, in which she documented that petitioner thought he had a prior reaction to Tdap in college that caused him to move like a zombie. *Id.* at 6; *see also* Pet. Ex. 4 at 371. Petitioner expressed to Dr. Young that he was “crucified” by the school where he was coaching and that he could “do miracles,” but was fired and accused of stealing others’ work. *Id.* Petitioner also explained that he felt “burned in his work and romantic relationships despite always doing his best.” *Id.* Petitioner also discussed “his tendency to shove his emotional pain ‘in the closet’ only to have it explode and burst open after the experience he had on the ‘reality show of Long Beach.’” *Id.*

Dr. Singer reviewed this background, noting that the petitioner had a history of depression which is commonly associated with psychosomatic illness and is seen as an amplifier of potential symptoms. *Id.* at 7. Dr. Singer stated that petitioner’s reference to “moving like a zombie” did not describe a medical condition and “had the flavor of a psychosomatic movement condition.” *Id.* at 7. He observed that petitioner was able to relate some of the physical pain to unresolved and unaddressed emotional issues, stating, “This is practicably the definition of a psychosomatic illness, namely conversion disorder.” *Id.* Dr. Singer related petitioner’s statement that he “shove[d] his emotional pain in the closet only to have it explode and burst open,” to a psychosomatic illness, “where buried and suppressed unconscious emotion wreak havoc on bodily function.” *Id.* Dr. Singer also observed that the petitioner’s sense of victimization is consistent with the psychological mechanism thought to underlie psychosomatization. *Id.* He explained that that in the petitioner’s statements about how he was accused of stealing others’ work and fired from his job and how petitioner used the term “crucified” to describe his treatment by the school where he was coaching are indicative of a sense of victimization. *Id.* Dr. Singer stated that victimization is a feeling of frustration that can be put into the body and experienced as pain and other illnesses. *Id.* at 8.

Dr. Singer opined, “Prior to the vaccine administration, the claimant was in good

health....Absent the [Tdap] shot, [petitioner] would not have suffered the physical and emotional pain he was experiencing during this time.” *Id.* at 9. However, when Dr. Singer made his assessment, he overlooked petitioner’s history of pre-existing musculoskeletal pain complaints, including those on the day of the vaccination. Additionally, Dr. Singer did not acknowledge that petitioner was experiencing emotional stress the day he received the vaccine, the same day he was referred to a mental health specialist.

As for the temporal association to petitioner’s pain and the vaccination, Dr. Singer stated that “prior to vaccination, the [petitioner] was in good health....The treating physicians opined that [petitioner] was suffering from a reaction to the tetanus vaccine.” *Id.* at 8. He concluded that petitioner’s reaction was made more severe and long-lasting as a result of [petitioner’s] probable psychosomatic conversion disorder, which amplified the symptoms for this patient.” *Id.*

G. Petitioner’s Pain Journal

On May 11, 2018, petitioner filed his pain journal as an exhibit. Pet. Ex. 8 (ECF No. 34). The pain journal begins on March 14, 2014 (the date of vaccination in question) with an entry stating, “appointment with Dr. Shic. Received barrage of boosters. Went home and within the hour felt intoxicated and slept hard till late next morning.” Pet. Ex. 8 at 1. Within the pain journal, discomfort and pain are noted immediately on March 15, 2014 with an entry of “[s]light [sic] of injection very sore. Felt very tired. Right shoulder very stiff and painful.” *Id.*

Over the course of March 2014, petitioner had similar symptoms with increasing levels of pain. Petitioner documents on March 27, 2014 that the pain was “near paralyzing” and his body was “hunched and look[ed] twisted.” *Id.* Throughout 2014, petitioner documented “[d]ifficulty walking” and the pain is described as located in his right rib cage on April 10, 2014. *Id.* at 2.

Over the course of the next several months, petitioner documents the level of pain and location on a daily basis (i.e. “Pain but somewhat tolerable,” “Still sore in shoulders and lower back,” “General soreness in shoulders to painful upper body,” “Exquisite pain in upper right buttocks,” etc.) as short entries on a calendar. Pet. Ex. 8 at 1-11. For the time period between March 14, 2014 and February 11, 2016, petitioner makes detailed entries for specific dates that document his activity and treatment during the day as well as how he feels. Some of the entries repeat verbatim for a period of a week to two weeks. Entries from April 10, 2014 through April 23, 2014 is exemplary of this:

“April 11, 2014: Pain in lower right rib cage, otherwise somewhat tolerable. Difficulty breathing, walking, sleeping.”

Pet. Ex. 8 at 2. This entry was repeated every day for the next two weeks.

Petitioner also submitted an affidavit affirming that the pain calendar was created at the time the events were occurring and not prepared in anticipation of litigation. Pet. Supp. Affidavit (ECF No. 38).

H. Petitioner’s Affidavit

On September 22, 2016, petitioner filed an affidavit. Pet. Affidavit (ECF No. 6). He

recalled that after receiving the vaccination he “began to feel unwell to the point of unconsciousness.” Pet. Aff. at ¶ 4. The following day, petitioner felt very sore and exhausted. *Id.* Two days later, petitioner stated that his jaw, shoulders and arms went into severe spasms that woke him up. *Id.* at ¶ 5. Petitioner stated that it felt “as if I was being skewered through the arm and shoulders. It felt as if my arms were pinned and my back and shoulders arched backward. It was difficult to walk and impossible to get any real sleep.” *Id.* at ¶ 6. Petitioner described the level of pain as ranging from “the feeling of [my] skin being pierced to the flesh being torn from the bone,” and it lasted until January 2015. *Id.* at ¶¶ 8-9. He explained that the most pain he experienced was along the right side of the sacrum and his entire right leg, affecting his mobility. *Id.* at ¶ 16. The petitioner indicated that prior to the vaccination, he was in his “usual health” with no fever. *Id.* at ¶ 14. He stated that he continued with physical therapy to strengthen and straighten his body from the injury. *Id.* at ¶ 17.

IV. Parties’ Arguments

A. Petitioner’s Motion for Ruling on the Record

Petitioner argued that following vaccination, he felt tired and sore the night of the vaccination. Pet. Mot. at 6 (citing Pet. Ex. 8 at 1). Over time, petitioner cites to his pain journal that muscle spasms and pain in the jaw, neck, and shoulders manifested. Pet. Mot. at 7. Petitioner also cited to the medical record where Dr. Shic and Dr. Gratton make references to petitioner’s vaccination as a suspected cause as well as the lack of an infection. *Id.* (citing Pet. Ex. 4 at 302, 322, 359). Petitioner asserted that the vaccine injury in question is the back, shoulder, and regional pain allegedly caused by the Tdap vaccine. *Id.* at 11-12.

Petitioner argued he does not have the burden of proving a specific scientific biological mechanism in order to prevail in his case, citing to *Knudsen*. Pet. Mot. at 6 (citing *Knudsen v. Sec’y of Health & Human Servs.*, 35 F.3d 543 (Fed. Cir. 1994)). Under prong one of *Althen*, petitioner recited the theories offered by Drs. Gershwin and Singer. *Id.* at 7-10. Under prong two of *Althen*, petitioner stated there was no alternate cause and offers the following sequence of events: (1) petitioner received the Tdap vaccination on March 14, 2014;²⁴ (2) petitioner experienced shoulder and back pain thereafter; (3) treating physicians stated that the condition was “likely [a] Tdap side effect;” (3) Drs. Gershwin and Singer opined that the timing of the aches was appropriate and made worse due to petitioner’s existing medical condition. Pet. Mot. at 10.

Under prong three of *Althen*, petitioner stated the proximate temporal relationship is met as petitioner received the vaccination on March 14, 2014 and reported symptoms beginning March 15, 2014. Pet. Mot. at 10-11; *see also* Pet. Ex. 8 at 1.

Petitioner also responded to Dr. Oddis’ expert report. Petitioner argued that Dr. Oddis discounted the petitioner’s complaints listed in the post-vaccination medical record and the notations of treating physicians who state petitioner’s pain was due to vaccination. Pet. Mot. at 13. Petitioner also argued that respondent has not offered evidence in support of alternate causation. *Id.* (citing *Pafford v. Sec’y of Health & Human Servs.*, 64 Fed. Cl. 19, 35 (2005), *aff’d*,

²⁴ Petitioner’s motion mistakenly states he received the “flu vaccine on the morning of March 14, 2014.” Pet. Mot. at 10. Petitioner received the Tdap and PPV vaccinations on March 14, 2014.

451 F.3d 1352 (Fed. Cir. 2006)).

B. Respondent's Response to Petitioner's Motion for Ruling on the Record

Following a recitation of the relevant medical facts, respondent first stated that petitioner has not established that he has suffered a medically-recognized injury by preponderant of the evidence. Resp. Response at 7; *see also Broekelschen*, 618 F.3d at 1346; *Lombardi v. Sec'y of Health & Human Servs.*, 656 F.3d 1343, 1352 (Fed. Cir. 2011). Respondent argued that petitioner's pain calendar is insufficient evidence of a vaccine-related injury because it does not contain any details prior to the vaccine, raising the question of the reliability of the calendar and it only contains subjective symptoms post-vaccine. *Id.* at 8. Respondent also stated that petitioner's experts, Drs. Gershwin and Singer do not actually identify a vaccine-related injury, rather they allege petitioner experienced a somatic reaction to the vaccination. *Id.* Respondent cited to *Ruiz*, *Reape*, *Pless*, and *Bailey* where somatic reactions to vaccinations were not found to be compensable. *Id.* at 8 (citing *Ruiz v. Sec'y of Health & Human Servs.*, No. 02-156V, 2007 WL 5161612 (Fed. Cl. Spec. Mstr. Mar. 14, 2007); *Reape v. Sec'y of Health & Human Servs.*, No. 151146V, 2017 WL 1246325 (Fed. Cl. Spec. Mstr. Mar. 3, 2017); *Pless v. Sec'y of Health & Human Servs.*, No. 16-271V, 2017 WL 836610 (Fed. Cl. Spec. Mstr. Feb. 6, 2017); *Bailey v. Sec'y of Health & Human Servs.*, No. 06-464V, 2008 WL 482359 (Fed. Cl. Spec. Mstr. Feb. 12, 2008)). Respondent stated that at best, petitioner showed a local reaction to vaccination, but no sequelae lasted more than six months, his pre-existing medical conditions explain the post-vaccination reaction, and somatic reactions are not compensable in the Vaccine Program. *Id.*

Then respondent argued petitioner has failed to meet his burden by preponderant evidence under the *Althen* test. Respondent asserted that neither Dr. Gershwin nor Dr. Singer stated a theory of causation connecting the petitioner's injury to the Tdap vaccine. *Id.* at 9. Respondent stated that Dr. Gershwin opined that petitioner suffered from fibromyalgia, vaccines do not cause fibromyalgia, and petitioner's somatic response led to his diffuse pain syndrome. *Id.* at 6. Respondent argued that Dr. Singer also does not provide a theory of causation but instead focuses only on the temporal relationship of the Tdap vaccination to petitioner's muscle aches. *Id.* at 10. Respondent stated that Dr. Singer did not provide any additional evidence as to why the timing of petitioner's alleged injury was medically appropriate, and this is insufficient to establish vaccine causation. *Id.*

Finally, respondent asserted that none of petitioner's treating physicians opined that the Tdap vaccination did cause petitioner a vaccine-related injury. Respondent acknowledged that some of petitioner's treating physicians made reference to the Tdap vaccination and petitioner's complaints relating back to the vaccination. *Id.* However, respondent observed that petitioner's treating physicians, like Dr. Gratton, stated, "With diffuse nature was not a localized allergy type reaction. He did not have typical allergy reaction from vaccination. It is difficult to know what occurred prior." *Id.* at 9-10; Pet. Ex. 4 at 559.

C. Petitioner's Reply

Petitioner filed a reply to Respondent's Response on August 27, 2018. Pet. Reply (ECF No. 42). Petitioner first argued that the pain journal is a reliable, sound piece of evidence as the journal started post-vaccination where petitioner felt far different from his pre-vaccination state.

Pet. Reply at 2. Petitioner argued that the pain calendar adds credibility to the complaints he made to treating physicians. *Id.*

Next, petitioner argued that the compensable vaccine-related injury was his “back and shoulder pain” following the vaccine made worse by his “preexisting psychological condition.” Pet. Reply at 2. Petitioner argued that respondent’s reliance on *Ruiz* and *Pless* is misplaced, arguing that those cases were concerned with the compensability of a psychological injury caused by vaccination. Petitioner asserted that he is not alleging a psychological injury but rather that the Tdap vaccination caused a localized response that was made worse by petitioner’s pre-existing psychological condition. *Id.*

Finally, petitioner responded to respondent’s criticism of Dr. Singer’s expert report. Petitioner argues that the majority of expert reports are conducted based on the medical records without an examination. *Id.* Additionally, Dr. Singer’s qualifications and background in neurotoxicology is uniquely suited to evaluate petitioner’s alleged injury. *Id.* at 4. Finally, petitioner noted that respondent did not file a responsive report to Dr. Singer’s report. *Id.*

V. Discussion

A. Onset of Petitioner’s Symptoms

Petitioner alleged that the Tdap vaccination he received on March 14, 2014 caused him to suffer a reaction diagnosed as “back pain, lumbar pain, shoulder pain, and sacral pain.” Petition at Preamble. However, the record establishes that these symptoms and other symptoms petitioner associated with the Tdap vaccine, pre-dated the vaccination.

Two years prior to the vaccination, petitioner had complained of low-back pain to Dr. Fortenko. Pet. Ex. 4 at 5-6. He continued to complain of lower-back pain from March to November 2011 in multiple telephone calls to his primary care health provider. *Id.* at 24-25; 31-32; 38. He also reported occasional hip pain. *Id.* at 50-51. An MRI performed on November 15, 2011 revealed multilevel spondylotic disc disease and facet joint arthropathy of the lumbar spine most severely involving the L4-5 and L5-S1 levels. *Id.* at 61.

In September 2013, petitioner saw Dr. Shic complaining of lower back without weakness and numbness or tingling after waking up. Pet. Ex. 4 at 190. Petitioner explained that an MRI in 2011 showed spondylotic changes and moderate to severe central stenosis at the L4-L5 and L5-S1 levels. *Id.* A physical exam showed petitioner had exquisite right sided lumbar tenderness. *Id.*

On October 2, 2013, petitioner called his primary care provider complaining of lower back pain. Pet. Ex. 4 at 197. Dr. Shic spoke to petitioner the following day where petitioner reported that his pain “has gotten remarkably better since this morning.” *Id.* at 200. Dr. Shic noted that petitioner’s low back is “likely due to degenerative joint disease vs. strain,” and encouraged petitioner to call back if exacerbation of the pain occurred. *Id.*

On March 14, 2014, the day petitioner received the Tdap vaccination, he had sought treatment for bilateral shoulder pain, jaw pain, right knee pain and a tick bite that occurred two weeks prior to the appointment. *Id.* at 262. Petitioner explained he experienced, “increased right

jaw, shoulder and arm stiffness after having been bitten by a deer tick.” *Id.* Petitioner also reported, “increased interpersonal stress with neighbor and female crew team he was coaching.” *Id.* Two days after the vaccination, an entry in petitioner’s pain journal for March 16, 2014 stated, “*Right shoulder and arm, right knee very stiff and painful. Great deal of pain around jaws and necks.*” Pet. Ex. 8 at 1 (emphasis added). On March 20, 2014, petitioner wrote, “Back arched, *left and right shoulders* and arms. *Jaw and neck, right leg very painful and extremely stiff.*” *Id.*

On April 19, 2014, petitioner had a follow-up appointment for symptoms “all over his body, especially in his upper body.” *Id.* at 325. Petitioner was evaluated by Dr. Jayaram. *Id.* She wrote that petitioner presented with pain in the right and left shoulders, pain in the hips to the thighs, hands feeling swollen and aching, and reduced range of motion of the bilateral shoulders. *Id.* at 326. Petitioner reported to Dr. Jayaram that he, “had [a] tick bite when working outdoors in early March. Got the tick out within minutes. Started to get aching pain in the right arm and jaw couple of days after the tick bite.” *Id.* The physical exam was recorded as “abnormal exam of both upper [extremities],” with “muscle tenderness of the upper arm.” He was diagnosed with bilateral shoulder joint pain and hip pain. *Id.* at 327. When petitioner saw his rheumatologist, Dr. Gratton, on April 21, 2014, petitioner again reported bilateral pain in the shoulders and upper arms and hips to thighs that “got worse after the [Tdap] injection.” *Id.* at 353.

The petitioner’s symptoms of right jaw pain, shoulder and arm stiffness that petitioner asserts began after the Tdap vaccination are the same symptoms that petitioner associated with a deer tick bite that occurred two weeks prior. In his affidavit, petitioner stated, “The night of March 16, 2014, I woke abruptly when my back, jaw, shoulder and arms went into severe spasm.” Pet. Aff. at ¶ 5. It may be that petitioner experienced these symptoms on the night of March 16, 2014, but he was already experiencing pain in his bilateral shoulders, arms and jaw prior to receiving the Tdap vaccination. Further, petitioner had a history of lower-back and hip pain that existed at least two years prior to the vaccination, as evidence in the petitioner’s medical records prior to receiving the vaccination and two MRIs showing multilevel spondylotic disc disease with progression.

The record establishes that most of petitioner’s symptoms of pain began prior to the vaccination and cannot be attributed to the Tdap vaccination he received on March 14, 2014.

B. Petitioner’s Injury

The petitioner has failed to establish that he suffered a “vaccine-related injury.” A petitioner asserting an “off-Table” injury must specify the vaccine-related injury and shoulders the burden of proof on causation. *Broekelschen* at 1346. Identifying an injury is prerequisite to applying the *Althen* analysis. *Id.* Petitioner must show that he suffers from a “defined” and “medically recognized” injury, not “merely...a symptom or manifestation of an unknown injury.” *Lombardi* at 1353. Medical recognition of the injury claimed is critical. *Id.* As the Federal Circuit reiterated in *Lasnetski*, a “petitioner needs to make a showing of *at least one defined and recognized injury*,” *Lasnetski v. Sec’y of Health & Human Servs.*, 696 Fed.Appx. 497, 504 (Fed. Cir. 2017) (emphasis added) (citing *Lombardi* at 1353).

When determining whether petitioner has adequately proven a demonstrable injury, special masters analyze petitioner’s complete medical records filed into the record. § 300aa-11(c)(2).

Medical records created contemporaneously with the events they describe are presumed to be accurate and complete such that they present all relevant information on a petitioner's health problems. *Cucuras*, at 1528. Subsequent statements made by third parties that contradict contemporaneous medical records are less persuasive to special masters than the medical records. *Campbell ex rel. Campbell v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (2006).

Petitioner argued that the vaccine injury is "back and shoulder pain, in addition to regional pain" and this injury is well documented in the medical records. Pet. Mot. at 11. Petitioner asserted that he had a somatic disorder which made him react physically to a confirmed local reaction more severely than he would have had he not had an existing somatic disorder. *Id.* Petitioner stated that his treating physician, Dr. Shic, noted that petitioner experienced a reaction to the Tdap vaccination. Petitioner made it clear that he was not alleging that the vaccine caused his psychological disorder, but rather it was his existing underlying psychological disorder that made him experience a more severe reaction. Pet. Reply at 2.

Respondent argued that petitioner does not have a compensable injury. Resp. Response at 9. Respondent stated that at best, petitioner showed a local reaction to vaccination, but no sequelae lasted more than six months, his pre-existing medical conditions explain the post-vaccination reaction, and somatic reactions are not compensable in the Vaccine Program. *Id.*

Here, petitioner does not allege a defined and recognized injury. Instead, petitioner argued his injury is "back and shoulder pain and regional pain," which was made worse by this psychological reaction. Pet. Mot. at 11. However, these are *symptoms* of a non-specific injury and do not constitute a defined recognized injury sufficient for compensation under the Act. A "vaccine-related injury" must "be more than just a symptom or manifestation of an unknown injury," because such a symptom or manifestation could indicate any number of different underlying injuries, each with its own pathology, making it impossible for the court to accurately determine causation. *See Lombardi* at 1352 (citing *Broekelschen* at 1349).

The treating doctors considered multiple diagnoses over the time course at issue in this case. Even though the petitioner's primary care physician, Dr. Shic, initially indicated petitioner experienced some reaction to the Tdap vaccination, neither him nor his rheumatologist, settled on a consistent condition or injury that could be related to the Tdap vaccination. Dr. Shic initially noted that petitioner likely experienced an "Adverse effect of drug. Note: likely tdap side effect," after petitioner reported "diffuse muscle cramping." Pet. Ex. 4 at 270. Later, however, Dr. Shic contacted the petitioner to explain to petitioner that he had diabetes, "which could explain some of your recent symptoms." *Id.* at 310. Petitioner's rheumatologist, Dr. Gratton, first diagnosed petitioner with bilateral bursitis, but also considered a differential diagnosis of polymyalgia rheumatica. Pet. Ex. 4 at 359. However, later Dr. Gratton stated, in a note to Dr. Linda May, "I am having a hard time at this point finding a treatable diagnosis for him. If his symptoms are the same [in] the pelvis region when I see him, do you have any thoughts at this point?" *Id.* at 551. Eventually, in September 2014, Dr. Gratton diagnosed petitioner with multiple joint pain and low back pain. Pet. Ex. 4 at 486. Subsequently, when petitioner presented to Dr. Gratton after a two-year gap in appointments, she diagnosed him with lumbar radiculopathy and hypertension. *Id.* at 559.

Petitioner's experts also did not identify a specific injury to which petitioner suffered following the Tdap vaccination. Dr. Gershwin stated that "it is more likely than not that [petitioner] did develop some myalgias following the Tdap," however, he continued by opining that petitioner was misdiagnosed with polymyalgia rheumatica, and a more appropriate diagnosis was "poorly controlled diabetes," and fibromyalgia. Pet. Ex. 7 at 1-2. Further, Dr. Gershwin stated, "I should note that vaccination does not produce fibromyalgia." *Id.*

Dr. Singer, a neuropsychologist, did not identify a defined or recognized injury either. Instead, Dr. Singer opined that petitioner may have been suffering from "brachial neuritis (a condition associated with the tetanus vaccine, see vaccine package insert), even though "the claimant did not receive a diagnosis of brachial neuritis." Pet. Ex. 9 at 8. However, there is nothing in the medical records to suggest that petitioner's doctors were considering brachial neuritis, nor are any of the symptoms petitioner was exhibiting after the vaccination consistent with brachial neuritis. Further, Dr. Singer's reference to brachial neuritis was well outside his field of expertise as a neuropsychologist.

Dr. Singer opined that petitioner was in good health prior to receiving the vaccine, but had an existing "probable psychosomatic conversion disorder," that made petitioner's "reaction more severe and long-lasting." Pet. Ex. 9 at 8. However, Dr. Singer ignored petitioner's pre-existing pain problems to support his conclusion that there was a temporal association between the vaccine administration and the onset of petitioner's symptoms. Pet. Ex. 9 at 8. The medical records demonstrate the petitioner was experiencing bilateral shoulder pain, right jaw pain, right knee pain and lower back pain the day he received the Tdap vaccine. Additionally, petitioner indicated he was experiencing stress in his life related to an interpersonal issue with a neighbor and a female crew team he had been coaching, so much so, that his primary care physician referred him to a mental health specialist. *See* Pet. Ex. 4 at 262, 265.

Petitioner's complaints of a migratory pain condition which none of his treating physicians could attribute to any particular injury or condition created a significant problem in demonstrating he suffered an immune mediated illness or mechanical injury that could be related to the vaccine. In the months following the vaccination, petitioner complained of right arm pain, then left arm then simultaneously both arms and shoulder pain as well as back, buttocks and leg pain, jaw pain and "exquisite wrist pain" all of which he attributes to a vaccine reaction. *See* Pet. Ex. 4 at 353, 423, 457. His low back, buttock and leg pain, at times referred to as sciatica, could easily be attributed to the MRI documented spondylotic disc disease, facet arthropathy, and spinal stenosis at L4-5 and L5-S1 with no causal relationship to the vaccination. *See* Pet. Ex. 4 at 507. His other symptoms are more difficult to categorize or relate to one another on a physiological basis.

To their credit, petitioner's experts, Dr. Gershwin and Dr. Singer did not propose a specific autoimmune or musculoskeletal diagnosis. Although Dr. Gershwin labeled petitioner's condition as fibromyalgia, not attributable to a vaccine, the focus of his report was on the petitioner's underlying psychological vulnerability, pre-existing musculoskeletal issues, misdiagnosis of an autoimmune disorder and consequent over-treatment leading to petitioner's mental fixation on the possibility of having a debilitating disease caused by the Tdap vaccine.

Dr. Singer's report also focused on petitioner's mental status at the time he received the

vaccine. Dr. Singer stated that petitioner had a “probable psychosomatic conversion disorder,” which amplified petitioner’s pain symptoms. However, Dr. Singer does not consider the vaccine to be the *cause* of petitioner’s conversion disorder-instead he attributes petitioner’s underlying, psychological vulnerabilities to be the cause of petitioner’s severe and long-lasting pain. Further, Dr. Singer’s only statement of vaccine causation is “there is a temporal relationship between the vaccine administration and the onset of symptoms,” which is insufficient alone to sustain a Vaccine claim. *See Althen*, 418 F. 3d at 1278.

In response to respondent’s argument that somatic reactions are not compensable, petitioner argued that his vaccine injury is generalized back and shoulder pain and not a psychological disorder, therefore respondent’s reliance on these cases were misplaced. Pet. Reply at 2. Petitioner specifically argues that the respondent’s reliance on *Ruiz* is misplaced. *Id.* In *Ruiz*, the Special Master dismissed the claim, finding that the petitioner had no organic basis for her symptoms, but instead was diagnosed with a conversion disorder. *Ruiz v. Sec’y of Health & Human Servs.*, No. 02-156V, 2007 WL 5161612 (Fed. Cl. Spec. Mstr. Mar. 14, 2007). The Court of Federal Claims affirmed the Special Master’s decision, finding that the petitioner failed to establish that the vaccine caused or significantly aggravated her psychological condition and only established a temporal proximity between the vaccine and the onset of her psychological condition. *Ruiz v. Sec’y of Health & Human Servs.*, 2007 WL 5161754, Fed. Cl. (2007). Respondent also cited to *Pless*, where the Special Master dismissed the case, finding that the petitioner’s treating physicians attributed her physical complaints to somatization instead of a vaccine-related injury. *Pless v. Sec’y of Health & Human Servs.*, No. 16-271V, 2017 WL 836610 (Fed. Cl. Spec. Mstr. Feb. 6, 2017). In *Pless*, the petitioner’s underwent numerous tests that came back normal and her treating physician suspected that petitioner had a functional somatic disorder. *Pless*, 2017 WL 836610*4. The respondent also cited to *Bailey*, where the former Chief Special Master Campbell-Smith, dismissed the petition, finding that the petitioner failed to establish that the flu vaccine caused him to suffer a post-vaccinal encephalopathy and reactive depression. *Bailey v. Sec’y of Health & Human Servs.*, No. 06-464V, 2008 WL 482359 (Fed. Cl. Spec. Mstr. Jan. 31, 2008). In *Bailey*, the petitioner’s treating physicians uniformly agreed that there was no evidence of a neurological basis for the petitioner’s complaints and it was suggested that petitioner was susceptible to somatoform disorders. 2008 WL 482359*7.

Petitioner’s case is no different than the cases discussed above. In *Ruiz*, *Pless* and *Bailey*, none of the petitioners’ treating physicians could identify a biological explanation for their alleged symptoms, but instead pointed to a psychological condition that may have explained their symptoms. Here, petitioner’s own treating physicians are unable to identify a physiological explanation for his pain symptoms, offering multiple explanations, including uncontrolled diabetes, lumbar spondylosis, osteoarthritis and even a self-reported tick bite that occurred two weeks prior to receiving the vaccine. It is petitioner’s experts that opined petitioner’s migratory pain complaints were better explained by a psychological reaction to multiple stressors in his life that happened to coincide with the administration of the Tdap vaccine.

The Vaccine Act requires a petitioner to allege a “defined and recognized injury,” that defines injury as a “vaccine-related injury” as an “illness, injury, condition or death.” §300aa-11(c); §300aa-333(5). While the Act does not require a petitioner to allege a specific diagnosis, a defined and recognized injury must be more than “merely a symptom or manifestation of an

unknown injury.” *Lombardi*, 656 F.3d at 1353. Here, petitioner has not presented evidence of a defined or recognized injury. Rather petitioner presented evidence of a series of migratory pain complaints (symptoms) to which his treating physicians are unable to attribute to a specified injury, illness or condition. Instead, petitioner’s treating physicians offer varying explanations for his migratory pains. Further, petitioner’s experts were unable to offer a physiological explanation for petitioner’s migratory pain and opined that petitioner’s pain was attributable to a psychological reaction to co-existing stressors in his life, including a transient reaction to the vaccine. The significant list of traumatic life events in the petitioner’s history provided more than fertile ground for somatization with the occurrence of the post vaccinal pain, providing a psychologically explanation for his somatic symptoms.

Petitioner has not shown a recognized injury, an autoimmune basis for his pain or a local mechanical injury to his left shoulder that persisted for more than six months. Thus, his condition cannot be causally related to the Tdap vaccine. Therefore, petitioner has not demonstrated a compensable injury to which three-pronged *Althen* analysis can be applied.

VI. Conclusion

The petitioner’s pain complaints can be attributed to both his pre-existing musculoskeletal history that is well documented in the medical record and also as a likely product of psychologically based symptom amplification. This is not to say that petitioner did not actually experience pain secondary to the complex. However, petitioner has failed to establish that the Tdap vaccine he received on March 14, 2014 was the cause of his migratory pain complaints. Further, the petitioner has failed to establish that his pain complaints manifested to a “recognized and definable injury,” as required by the Vaccine Act.

Accordingly, the petitioner is not entitled to compensation and the petition is **DISMISSED**.

IT IS SO ORDERED.

s/Thomas L. Gowen
Thomas L. Gowen
Special Master